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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,082	07/17/2006	Katsura Funayama	2006_0715A	1245

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EXAMINER	
GULLEDGE, BRIAN M	

ART UNIT	PAPER NUMBER
4161	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,082	FUNAYAMA ET AL.	
	Examiner	Art Unit	
	Brian Gulledge	4161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *1-12* is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Claims 1-12 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be December 9, 2004, the filing date of the parent application PCT/JP04/18369.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 8, and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabling for treating obesity in a subject comprising administering to the subject an extract of *Ascophyllum nodosum*, does not reasonably provide enablement for preventing obesity in a subject. The specification does not enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount of direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While the Examiner has considered all of these factors, a sufficient amount for a *prima facie* case are discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of preventing obesity in a mammal, comprising the steps of administering to said subject a lipase inhibitor comprising an extract of *Ascophyllum nodosum*. The nature of the invention is extremely complex in that it encompasses the actual prevention of obesity disorder such that the subject treated with the above extract does not *ever* suffer from obesity. Please note when prevention is recited that it is supposed to never occur in the first instant.

Breadth of the claims: The complex of nature of the claims is greatly exacerbated by their breath. The claims encompass prevention of obesity in a subject which has potentially many different causes (i.e. many different combinations of symptoms, different medical disorders or diseases, different chemical toxins and enzymes), each of which may or may not be addressed by the administration of the claimed extract.

Amount of direction presented: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually prevent obesity is minimal. All of the guidance provided by the specification is directed towards treatment rather than prevention of obesity.

Working examples: All of the working examples provided by the specification are directed toward the treatment rather than prevention of obesity.

Predictability of the art: The lack of significant guidance from the specification or from the prior art with regard to the actual prevention of obesity in a mammal with the claimed extract makes practicing the claimed invention unpredictable in terms of prevention of obesity.

The quantity of experimentation necessary: In order to practice the claimed invention, one of ordinary skill in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc., an appropriate animal model, and determine when preventing should start with one of the claimed compounds and then test the above determined combination in the model system to determine whether or not the compound is effective for prevention of obesity in the said population type. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regarding prevention of obesity with any compound, one of skill in the art would have to then either envision a modification of the extract, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, and test the system again.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The steps of combining and or mixing ingredients to produce a medicine, or food, by preparing an extract are not included in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-8, and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Barwell et al. (C.J. Barwell, G. Blunden, P.D. Manandhar, "Isolation and Characterization of Brown Algal Polyphenols as Inhibitors of α-Amylase, Lipase, and Trypsin," J. App. Phycology, 1989, 1, pages 319-323).

Barwell et al. discloses an extract of *Ascophyllum nodosum* that inhibits lipase (page 320, Table 1, line 8), and that a purified substance from the same algae also inhibits lipase (page 321, Table 3, line 10). These results anticipate the recited inhibitor of instant claims 1 and 2.

Instant claim 3 further recites the extract in the form of food and drink, and Barwell et al. anticipates this limitation with the disclosed use of the algal extract as a human 'health food' (page 322, right column, paragraph 2, line 3). This disclosure also anticipates instant claim 4 and 5, which recites the inhibitor in the form of healthy food.

Instant claim 7 recites a method of inhibiting lipase activity, comprising administering an extract of *Ascophyllum nodosum* to a mammal. Barwell disclosed the use of an extract of *Ascophyllum nodosum* (and showed it as a lipase inhibitor, see above) to humans (a mammal), as stated above, thus anticipating instant claim 7. Barwell further discloses that feeding pigs and sheep with a meal derived from this algae that "weight gain becomes less than with unsupplemented food" (page 323, paragraph 1, lines 2-3). This disclosure anticipates instant claim 8, as it shows a method of treating obesity (reduced weight-gain) in a mammal (pig), comprising administering an extract of *Ascophyllum nodosum*.

Instant claims 10-12 recite a method for producing a medicine or food and drink that comprises the step of preparing an extract of *Ascophyllum nodosum*. Barwell et al. discloses a method of preparing extracts of algae, including *Ascophyllum nodosum* (page 319/paragraph 3 – page 320/paragraph 1), and their use in feed-stuffs (page 322, right column, paragraph 2, lines 1-3), thus anticipating instant claims 10-12.

Claims 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Barwell et al. (C.J. Barwell, G. Blunden, P.D. Manandhar, "Isolation and Characterization of Brown Algal Polyphenols as Inhibitors of α-Amylase, Lipase, and Trypsin," J. App. Phycology, 1989, 1, pages 319-323) and as evidenced by Ballinger et al. (A. Ballinger and S.R. Peikin, "Orlistat: its current status as an anti-obesity drug," Eur. J. Pharma. 2002, 440, pages 109-117). Instant claim 6 recites the extract of *Ascophyllum nodosum* being a plasma-triglyceride agent. Barwell et al. discloses this extract, as discussed above, but is silent on the effect of the extract on plasma triglycerides. However, Ballinger et al. states that lipase is critical for the digestion of triglycerides (abstract, line 1), and a lipase inhibitor inhibits the fat

absorption (abstract, lines 2-3), which lowers triglyceride levels. Thus, it is an inherent property of the extract from *Ascophyllum nodosum,* disclosed by Barwell et al., that it lowers plasma triglycerides, thus anticipating instant claim 6.

Instant claim 9 recites a method of lowering plasma triglyceride, comprising administering an extract of *Ascophyllum nodosum*. Barwell et al. discloses the use in mammals of the instantly recited extract, as stated above, but is silent on the use of the extract to lower plasma triglyceride levels. But as evidence by Ballinger et al., the use of this lipase inhibitors disclosed by Barwell et al. inherently reduces plasma triglyceride levels.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gulledge whose telephone number is (571) 270-5756. The examiner can normally be reached on Monday-Thursday 7:00am - 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BMG

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4161